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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,371	03/28/2001	Kohji Egawa	31508	4334
7590	07/07/2004		EXAMINER	CANELLA, KAREN A
John M. Collins HOVEY, WILLIAMS, TIMMONS & COLLINS Suite 400 2405 Grand Blvd. Kansas City, MO 64108			ART UNIT	PAPER NUMBER
1642				
DATE MAILED: 07/07/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/819,371	EGAWA, KOHJI
Examiner Karen A Canella	Art Unit	
	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 34-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 34-36 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. ____ .   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/3/2004</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____ .                                   |

### **DETAILED ACTION**

Acknowledgement is made of applicants election of SEQ ID NO:3 and 6. The restriction requirement mailed March 25, 2004 is withdrawn in light of the instant pending claims.

Claims 14-33 and 37-38 have been canceled. Claims 34-36 are pending and examined on the merits.

#### ***Priority***

Acknowledgment is made to applicants claim to foreign priority via Japanese Patent application 11-279566, filed September 30, 1999. However, the filing date of the instant application is March 28, 2001 and is more than one year after the foreign priority filing date. Neither the specification, the oath nor the bibliographic data sheet have identified an intervening US application or PCT designating the US that was filed within a year of the foreign priority document. It is concluded that applicants claim to the foreign priority document is not valid and will not be considered.

#### ***Specification***

The specification is objected to for lacking sequence compliance on page 12, line 4, 6, 9, 11, page 16, lines 19-20, and page 20, lines 9 and 10.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 lacks an active method step which links the detection of the HLA-F antibody with the method objective of diagnosing cancer as recited in the method objective. The recitation of “the individual” in the last line lacks antecedent basis within the claim. It is unclear how “part of an immunological pair which can form an immune complex” can be used in a competitive reaction with an antibody in a body fluid as both “parts” of the immunological pair, the HLA-F antigen and the anti-HLA-F antibody, would be required for the competitive reaction: the HLA-F antigen for binding to the HLA-F antibody in the body fluid and the HLA-F antibody within the “immunological pair” to compete with the HLA-F antibody in the body fluid. In line 3, it is unclear what “it” is in reference to, whether it refers to the immunological pair, the immune complex or the HLA-F antigen. For purpose of examination “it” will be read as the HLA-F antigen.

Claim 35 is vague and indefinite as it is dependent upon a canceled claim.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morin et al (WO 01/75177, priority to 60/194,336, April 3, 2000) in view of Sasse et al (US 4,235,960).

Claim 34 is drawn to a method of diagnosing cancer comprising competitively reacting an immunological pair comprising a HLA-F antigen, or part of an HLA-F antigen and anti-HLA-F antibody, or antigen binding fragment thereof with the body fluid of the subject wherein detection of an anti-HLA-F antibody in the body fluid of the subject by means of competition with the anti-HLA-F antibody in the immunological pair is indicative of cancer in the subject.

Claim 36 embodies the method of claim 34 wherein the body fluid is blood.

Morin et al teach the diagnosis of ovarian cancer by means of detecting the ovarian cancer antigen of Sequence Identifier 82. Sequence identifier 82 comprises residues 22-295 of the instant SEQ ID NO:5 and residues 44-258 of SEQ ID NO:6. Morin et al teach that the antigens of the invention were identified by a SAGE assay which were validated as implicated in immune response pathways(page 7, lines 1-3), thus it can be concluded that the tumor marker antigens were immunogenic in patients. Morin et al teach that ovarian tumor marker polypeptide-specific autoantibodies levels that are at least about 3-fold higher than in a control sample are indicative of ovarian cancer (page 16, lines 1-7).

Sasse et al (US 4,235,960) teach a competitive enzyme-linked immunoassay (abstract and column 1, lines 10-57) which is both specific and sensitive.

It would have been *prima facie* obvious at the time the claimed invention was made to detect autoantibodies which bind to the ovarian cancer antigen of Sequence Identifier 82 by means of a competitive immunoassay. One of skill in the art would have been motivated to do so by the teachings of Sasse et al on the sensitivity and selectivity of competitive immunoassays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

6/28/2004

*Karen A. Canella*  
KAREN A. CANELLA PH.D  
PRIMARY EXAMINER